

PATENT COOPERATION TREATY

Ploughmann & Vingtoft

28 JULI 2005

From the INTERNATIONAL SEARCHING AUTHORITY

PCTHEM/CHS

To:

PLOUGHMANN & VINGTOFT A/S
 Sundkrogsgade 9
 P.O. Box 831
 DK-2100 Copenhagen
 DENMARK

NOTIFICATION OF TRANSMITTAL OF
 THE INTERNATIONAL SEARCH REPORT AND
 THE WRITTEN OPINION OF THE INTERNATIONAL
 SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing (day/month/year) 28/07/2005	
Applicant's or agent's file reference 35818 PC 01	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/DK2005/000063	International filing date (day/month/year) 28/01/2005
Applicant FERROSAN A/S	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders


Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority  European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Jaap Hurenkamp
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NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PATENT COOPERATION TREATY

PCT

Plougmann & Vingtoft

28 JULI 2005

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 35818 PC 01	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/DK2005/000063	International filing date (day/month/year) 28/01/2005	(Earliest) Priority Date (day/month/year) 30/01/2004
Applicant FERROSAN A/S		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (See Box II).

3. ☐ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

- b. ☒ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/DK2005/000063

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 930 052 A (DE BROU ET AL) 30 December 1975 (1975-12-30) cited in the application column 2, line 3 - line 29 column 2, line 54 - line 62 column 3, line 7 - line 21 claims 1,14	37,40-43
X	US 6 045 570 A (EPSTEIN ET AL) 4 April 2000 (2000-04-04) cited in the application column 7, line 33 - line 66 claims 1-11	1-10,23, 24,26, 34-36
X	WO 03/055531 A (FERROSAN A/S; WOLFF, JOERGEN) 10 July 2003 (2003-07-10) the whole document	1-17, 26-30, 34-36
X	GB 1 584 080 A (ETHICON INC) 4 February 1981 (1981-02-04) page 1, right-hand column, line 74 - line 99 page 2, left-hand column, line 12 - line 48 examples 1,2 claims 1-14	1-4,6,7, 11,18, 20,22, 25,26, 30,32-36
X	WO 03/007845 A (BAXTER INTERNATIONAL, INC; BAXTER HEALTHCARE S.A; BAXTER INTERNATIONAL) 30 January 2003 (2003-01-30) the whole document	37-49
A	PATENT ABSTRACTS OF JAPAN vol. 013, no. 381 (E-810), 23 August 1989 (1989-08-23) & JP 01 130519 A (MITSUBISHI ELECTRIC CORP), 23 May 1989 (1989-05-23) abstract	1-49
A	EP 0 372 966 A (JOHNSON & JOHNSON PATIENT CARE, INC; JOHNSON & JOHNSON MEDICAL; INC) 13 June 1990 (1990-06-13) the whole document	1-49

INTERNATIONAL SEARCH REPORT

International Application No

PCT/DK2005/000063

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L15/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K A61J A61M A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/012741 A1 (FURLAN DIEGO ET AL) 16 January 2003 (2003-01-16) cited in the application	1,2,11, 13,14, 16,17, 25,27-33
Y	page 1, paragraph 11 - paragraph 12 page 1, paragraph 15 - page 2, paragraph 29 examples 1-4 claims 1-14	10,12, 18-24, 26,37-49
X	US 5 951 531 A (FERDMAN ET AL) 14 September 1999 (1999-09-14)	1-9,11, 13-17, 25,27-36
Y	the whole document	10,12, 18-24, 26,37-49

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

18 July 2005

Date of mailing of the international search report

28/07/2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Menidjel, R

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK2005/000063

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 32 and 49 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/DK2005/000063

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2003012741	A1	16-01-2003	IT MI20000246 A1	16-08-2001
			AT 296859 T	15-06-2005
			CA 2395709 A1	23-08-2001
			CN 1446261 A	01-10-2003
			DE 60111192 D1	07-07-2005
			WO 0160922 A1	23-08-2001
			EP 1263884 A1	11-12-2002
			EP 1541634 A1	15-06-2005
			JP 2003523438 T	05-08-2003
US 5951531	A	14-09-1999	AU 6705894 A	08-11-1994
			WO 9423788 A1	27-10-1994
US 3930052	A	30-12-1975	FR 2167197 A1	24-08-1973
			AU 470354 B2	11-03-1976
			AU 5082673 A	11-07-1974
			BE 793847 A1	02-05-1973
			CH 574715 A5	30-04-1976
			DE 2264154 A1	19-07-1973
			ES 410479 A1	01-01-1976
			GB 1413873 A	12-11-1975
			IT 989521 B	10-06-1975
			JP 48080767 A	29-10-1973
			JP 53028979 B	17-08-1978
			NL 7300180 A ,B,	12-07-1973
			SE 394364 B	27-06-1977
			ZA 7209098 A	26-09-1973
US 6045570	A	04-04-2000	US 5951589 A	14-09-1999
			US 5922009 A	13-07-1999
			US 5806536 A	15-09-1998
			EP 1115336 A1	18-07-2001
			WO 0018301 A1	06-04-2000
			AU 5329699 A	21-02-2000
			EP 1100383 A1	23-05-2001
			WO 0006031 A1	10-02-2000
			AU 6274598 A	26-08-1998
			CA 2280914 A1	13-08-1998
			CN 1247460 A ,C	15-03-2000
			EP 0967922 A1	05-01-2000
			JP 2002513308 T	08-05-2002
			WO 9834546 A1	13-08-1998
			US 6056769 A	02-05-2000
			US 6056770 A	02-05-2000
			US 2003163146 A1	28-08-2003
			US 6464712 B1	15-10-2002
			US 2004176798 A1	09-09-2004
WO 03055531	A	10-07-2003	AU 2002367086 A1	15-07-2003
			CA 2470684 A1	10-07-2003
			WO 03055531 A2	10-07-2003
			EP 1458425 A2	22-09-2004
			HU 0402322 A2	29-03-2005
			JP 2005512734 T	12-05-2005
GB 1584080	A	04-02-1981	CA 1119515 A1	09-03-1982
			DE 2852319 A1	07-06-1979
			FR 2410477 A1	29-06-1979

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/DK2005/000063

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
GB 1584080	A		HK 34681 A	24-07-1981
			HU 179969 B	28-01-1983
			IE 47606 B1	02-05-1984
			IL 56110 A	13-09-1981
			IN 149490 A1	26-12-1981
			MY 5682 A	31-12-1982
WO 03007845	A	30-01-2003	US 2003064109 A1	03-04-2003
			BR 0211258 A	27-07-2004
			CA 2453592 A1	30-01-2003
			CN 1555249 A	15-12-2004
			EP 1414370 A1	06-05-2004
			JP 2005500102 T	06-01-2005
			WO 03007845 A1	30-01-2003
JP 01130519	A	23-05-1989	NONE	
EP 0372966	A	13-06-1990	US 4891359 A	02-01-1990
			AT 103187 T	15-04-1994
			AU 623456 B2	14-05-1992
			AU 4603789 A	14-06-1990
			CA 2004739 A1	08-06-1990
			DE 68914110 D1	28-04-1994
			DE 68914110 T2	07-07-1994
			EP 0372966 A2	13-06-1990
			ES 2062041 T3	16-12-1994
			IE 62927 B1	08-03-1995
			JP 2218616 A	31-08-1990
			JP 3195335 B2	06-08-2001
			ZA 8909372 A	28-08-1991

PATENT COOPERATION TREATY

Plougmann & Vingtor

From the
INTERNATIONAL SEARCHING AUTHORITY

28 JULI 2004

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/DK2005/000063

International filing date (day/month/year)
28.01.2005

Priority date (day/month/year)
30.01.2004

International Patent Classification (IPC) or both national classification and IPC
A61L15/32

Applicant
FERROSAN AS

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☐ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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10/587767

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/DK2005/000063

AP20 Received 28 JUL 2006

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

PCT/DK2005/000063

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- For the assessment of the present claims 32 and 49 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 - The following documents (D1-D7) are referred to in this communication (Article 33(6) PCT); the numbering will be adhered to in the rest of the procedure:

- D1: US 2003/012741 A1 (FURLAN DIEGO ET AL) 16 January 2003 (2003-01-16)
- D2: US-A-5 951 531 (FERDMAN ET AL) 14 September 1999 (1999-09-14)
- D3: US-A-3 930 052 (DE BROU ET AL) 30 December 1975 (1975-12-30)
- D4: US-A-6 045 570 (EPSTEIN ET AL) 4 April 2000 (2000-04-04)
- D5: WO 03/055531 A (FERROSAN A/S; WOLFF, JOERGEN) 10 July 2003 (2003-07-10)
- D6: GB-A-1 584 080 (ETHICON INC) 4 February 1981 (1981-02-04)
- D7: WO 03/007845 A (BAXTER INTERNATIONAL, INC; BAXTER HEALTHCARE S.A; BAXTER INTERNATIONAL) 30 January 2003 (2003-01-30)

2. Novelty (Article 33(2) PCT)

- The subject-matter of present claims 1-18,20,22-49 is considered as not novel over the cited prior art (Article 33(2) PCT):

- Document D1, cited by the applicant, describes a process for the preparation of micronised collagen powder, the collagen powder having a particle size of not more than 20 microns and a spray device to apply it (Cf. D1, page 1, paragraphs 11-12; page 1, paragraph 15-page 2, paragraph 29; examples 1-4; claims 1-14).

The subject-matter described in document D1 takes away novelty of present claims 1,2,11,13,14,16,17,25,27-33.

- Document D2 refers to a particulate haemostatic agent comprising collagen powder, a method to obtain it and a spray device to apply it (Cf. D2, the whole document).

The subject-matter described in document D2 takes away novelty of present claims 1-9,11,13-17,25,27-36.

- Document D3, cited by the applicant, relates to a composition comprising gelatine particles having a mean particle size of at least 10 microns, wherein said composition is in the form of a gel (Cf. D3, column 2, lines 3-29; column 2, lines 54-62; column 3, lines 7-21; claims 1,14). The subject-matter described in document D3 takes away novelty of present claims 37,40-43.

- Document D4, cited by the applicant, describes a gelatin powder including GelfoamTM, thrombin and saline water dispensed with a syringe (Cf. D4, column 7, lines 33-66; claims 1-11).

The subject-matter described in document D4 takes away novelty of present claims 1-10,23,24,26,34-36.

- Document D5 refers to a haemostatic kit, a method of preparing a haemostatic agent and a method of promoting haemostasis by using collagen or gelatin powder (Cf. D5, the whole document).

The subject-matter described in document D5 takes away novelty of present claims 1-17,26-30,34-36.

- Document D6 describes a haemostatic composition comprising collagen and fibrin powder (Cf. D6, page 1, right-hand column, line 74-line 99; page 2, left-hand column, line 12-line 48; examples 1,2; claims 1-14).

The subject-matter described in document D6 takes away novelty of present claims 1-4,6,7,11,18,20,22,25,26,30,32-36.

- Document D7 relates to a gelatin hydrogel formed from gelatin powder for promoting haemostasis (Cf. D7, the whole document).

The subject-matter described in document D7 takes away novelty of present claims 37-49.

3. Inventive Step (Article 33(1),(3) PCT)

a - Since the subject-matter of present claims 1-18,20,22-49 is known, it can obviously not be considered as inventive (Article 33(1),(3) PCT).

b - The remaining subject-matter, which is the subject-matter of present claims 19 and 21 does not involve an inventive step for the following reasons (Article 33(1),(3) PCT):

- The subjective problem to be solved by the present application is to provide a haemostatic spray which contain a material suitable for effecting haemostasis and at the same time is more biocompatible.

- The solution proposed in the present application is a "ready-to-use" haemostatic spray which may be used acute as well as prophylactic as described in the present application.

- Document D2, which is considered as the closest prior art, describes a particulate haemostatic agent comprising collagen powder, a method to obtain it and a spray device to apply it (Cf. D2, the whole document).

- The difference between the teaching of the closest prior art and the subject-matter of present claims 19 and 21 appears to be the presence of an adhesive agent selected from the group consisting of sucrose, glucose and combination thereof and wherein said agent is coated on the surface of said powder.

- The feature of present claims 19 and 21 is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

Therefore, the subject-matter of present claims 19 and 21 does not involve an inventive step (Article 33(1),(3) PCT).

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